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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,346	04/15/2005	Stefan Frahling	GIL-16027	8225
7609 7590 02/01/2010 RANKIN, HILL, & CLARK LLP 23755 Lorain Road - Suite 200 North Olmsted, OH 44070-2224				
EXAMINER				
PALENIK, JEFFREY T				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
02/01/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,346

Applicant(s)

FRAHLING ET AL.

Examiner

Jeffrey T. Palenik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,10,15-20 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,10,15-20 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

STATUS OF APPLICATION

Receipt is acknowledged of Applicant's After Final Amendment and Remarks filed on 20 January 2010, in response to the FINAL rejection mailed on 20 November 2009, in the matter of Application N° 10/531,346. Applicants' remarks and previously presented claims are entered on the record. The Examiner further acknowledges the following:

Applicant has essentially requested reconsideration of the finality of the last Office action on the grounds that the product-by-process limitations of molding and freeze-drying the article applied in the method lend criticality to the instant invention, namely that a porous structure which is devoid of water is being claimed as the composition used rather than the solid article which becomes lubricated in the Kojima reference. **The Examiner has reconsidered the art of record and in view of Applicants' remarks which are persuasive** in denoting the differences between the products implemented in the method and that which is disclosed in the art, **hereby withdraws finality of the previous action.**

Regarding Applicant's presently entered claims:

No claims have been amended, cancelled or added.

Thus, no new matter has been added.

Claims 1, 4-6, 10, 15-20 and 23 continue to represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been filed for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Rejection under 35 USC 103(a)

Applicants' remarks, as discussed above, are sufficient to render moot the obviousness rejection made to claims 1, 4-6, 10, 15-20 and 23 as being unpatentable over the teachings of Kojima et al. (USPN Pre-Grant Publication N° 2002/0068683). Since the Kojima has been successfully argued as resulting in a product which is structurally distinct to the product of the instant invention (i.e. criticality shown in the product-by-process steps), it is considered as no longer reading on the instant invention. Said rejection now stands **withdrawn**.

NEW OBJECTIONS/REJECTIONS

In light of Applicants' remarks and the above withdrawn rejection, the following rejection is newly added:

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6, 10, 15-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Zecchino et al. (USPN 6,497,887) in view of Kojima et al.

The instant claim 1 is directed to a method of using a shaped article to apply at least one skeleton-forming agent to an external skin or hair surface of a human or animal comprising (1) providing a sized and shaped article, free of protein-based scaffolding agent, (2) disintegrate said article with an aqueous solution to form a solution or a gel, and (3) applying the composition to the intended surface. Said shaped article is further claimed as having a volume ranging from 100 microliters to 6 mL and a diameter ranging from 3-60 mm. The skeleton-forming agent recited in claim 1, is further recited as comprising at least one polysaccharide such as sodium alginate (claims 4 and 5). Claim 6 recites the article as sphere-shaped prior to contact with water (claim 6). Claim 10 further limits the method at step (b) of claim 1 such that the aqueous solution which contacts the article (e.g. wetting solution) further comprises an active or auxiliary substance. Said substances are further delineated in claims 15 and 16, respectively. The shaped

article is recited as further comprising one or more cosmetic or pharmaceutically active substances (claims 17 and 18) or one or more auxiliary substances such as squalane (claims 17-20). Claim 23, which depends from claim 10, further limits the article of claim 1 in the same manner as claim 17.

The invention of Zecchino anticipates the instantly claimed invention with the exception that Applicants' volumetric limitations are not expressly disclosed. The Abstract of Zecchino expressly discloses that the invention is directed to a delivery system for topical application to the skin comprising a freeze-dried membrane which can be reversibly returned to a dissolvable gel form upon the application of a wetting agent. Biologically active agents are released to the skin. Concerning the actual composition used by the instant method, Example 2 teaches a freeze-dried membrane (e.g. a shaped structure) which comprises both sodium alginate and squalane. The formulation is free of ingredients which are consistent with Applicants' definition of "protein-based skeleton forming agents" (i.e. enzymes, hormones, etc.) (see pg. 8, lines 5-9 of Applicants' specification). The limitations of claims 17-19 are also expressly taught by the formulation of Example 2. Potassium carbonate is well-known in the art as an alkalizing agent (i.e. a pH-adjusting agent). Rayon and hyaluronic acid are both well-known humectants; the former is also a plasticizer whereas the latter is also a lubricant. The cellulose gum is taught as a film-forming auxiliary substance (col. 3, lines 24-38). The limitations of claim 18 are met by Example 2 with the teaching of soluble collagen protein. "Soluble collagen", as defined by the art (see *Hawley's Condensed Chemical Dictionary*, 13th Ed.), is a "fibrous protein constituting most of the white fiber in the connective tissues of animals and humans, especially in the skin muscles and tendons" (pg. 288, Hawley's). Nowhere is it indicated that soluble collagen is a

“protein-based skeleton-forming agent”, as defined by Applicants. Regarding the limitations of claims 10, 15 and 16, Zecchino teaches that in order to function on the skin, the prepared membrane must be rewetted with a wetting solution or activator (col. 3, line 57 to col. 4, line 13). It is further taught as being preferred that the applied wetting solution be slightly acidic (e.g. pH of 2-6) in order to facilitate dissolution of the matrix and that any aqueous solution containing a cosmetically or pharmaceutically acceptable acid will be appropriate for use in rewetting. Examples of different cosmetically or pharmaceutically acceptable acids such as malic acid are taught (col. 4, lines 6-13; Example 1).

Despite anticipating the chemical composition and method of application of the instant invention, the Zecchino reference is deficient in its teachings of both the volumetric limitations recited in step (a) of claim 1 and the geometrical sphere shape as recited in claim 6 by Applicants.

Regardless, a clear case of *prima facie* obviousness exists since the ordinarily skilled artisan would have been highly motivated to arrive at both the instantly claimed method and the composition used therein as evidenced by the express teachings discussed above.

Concerning the aforementioned deficiencies of Zecchino, since the volumetric ranges and geometric format of the article with respect to the claimed composition are adjustable, it follows that each is a parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. In the instant case, Zecchino expressly teaches in Example 1 that the article produced is a lyophilized membrane wafers which are sliced to a thickness of 0.5 mm. Formation of any desired freeze-dried shape is also expressly taught and suggested (col. 3, lines

39-55). Though the specific shape of a sphere is not taught, the formation of wettable objects is any shape is well known in the art, as evidenced by the previous teachings (e.g. Figure 6F) of Kojima et al. (US Pre-Grant Publication N° 2002/0068683). Thus, it would have been customary for an artisan of ordinary skill, to adjust the size and shape of in the composition used by the method, particularly in view of the forgoing teachings, in order to achieve the desired composition and method. See also MPEP §§2144.04(IV)(A.) and 2144.05. Thus, absent some demonstration of unexpected results or criticality from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

All claims under consideration remain rejected; no claims are allowed.

CONCLUSION

Due to the new grounds of rejection, this action is deemed **non-final**.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615